IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090 and *The County of Cuyahoga v. Purdue Pharma L.P., et al.* Case No. 1:18-op-45004	MDL No. 2804 Hon. Judge Dan A. Polster

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' DAUBERT MOTION TO EXCLUDE THE OPINIONS OF SETH B. WHITELAW

I. INTRODUCTION

Defendants move to exclude the opinions of Seth Whitelaw, proffered by plaintiffs as an expert on DEA suspicious order monitoring. Whitelaw lacks any experience with controlled substances, pharmaceutical distribution, the Controlled Substances Act, or the Drug Enforcement Administration ("DEA"). He never designed, operated or audited a suspicious order monitoring program for controlled substances. He never worked at DEA. He never worked for a pharmaceutical distributor or a manufacturer of controlled substances. Instead, Whitelaw is a food and drug attorney who advises clients on the routine regulations of the Food and Drug Administration ("FDA"). In short, Whitelaw lacks the qualifications, training, and experience to serve as an expert on DEA suspicious order monitoring programs. Indeed, Whitelaw admits that, prior to this litigation, he did not consider himself an expert in suspicious order monitoring.

In addition to being unqualified, Whitelaw's methodology is unreliable. He created a model suspicious order monitoring program relying on a regulatory framework of his own invention that is not used either by those in the field or by DEA and was created solely for the purposes of this litigation. Whitelaw relies on what he describes as the "eight elements" of the Federal Sentencing Guidelines for organizations convicted of felonies and misdemeanors as the basis for his analysis. But the Federal Sentencing Guidelines are not about suspicious order monitoring or the diversion of prescription medications; instead, they provide courts with guidelines for the sentencing of organizations for felony and Class A misdemeanor offenses. Neither DEA nor industry participants—nor anyone else—uses the Federal Sentencing Guidelines to evaluate suspicious order monitoring programs.

Whitelaw's opinions are, in short, made up out of whole cloth as a litigation-based exercise with no grounding in the real world. This is confirmed by the fact that after Whitelaw

was retained by plaintiffs in this case, he reversed his earlier published criticisms against the use of government guidance and standards as a basis for compliance programs.

Whitelaw should be excluded because he is not qualified to be an expert on DEA suspicious order monitoring programs, his opinions are unreliable, and he purports to usurp the role of the jury by opining on an ultimate issue.

II. WHITELAW'S BACKGROUND, OPINIONS, AND METHODOLOGIES

A. Whitelaw's Background.

Whitelaw is a self-proclaimed "licensed food and drug attorney." Ex. 1 (Whitelaw Rpt.) at 279. He worked for over 20 years as a food and drug attorney in private practice and in the compliance departments at life science companies—none of which manufacture or distribute controlled substances. Ex. 1 (Whitelaw Rpt.) at 279-81; Ex. 2 (Whitelaw Tr.) at 67:11-68:6, 70:7-22, 74:12-75:7, 76:21-77:6, 82:22-83:6.[1] Whitelaw is the sole employee of his own consulting firm, Whitelaw Compliance Group, LLC. Ex. 1 (Whitelaw Rpt.) at 279. Whitelaw describes his company as "[f]ocused exclusively on small to medium-sized FDA-regulated companies." Ex. 1 (Whitelaw Rpt.) at 279; Ex. 2 (Whitelaw Tr.) at 83:18-84:2. Whitelaw's company does not offer services related to the Controlled Substances Act or suspicious order monitoring programs. Ex. 3 (Whitelaw Compliance Group, LLC website).

Whitelaw's compliance experience is limited to regulations of the FDA—regulations that deal with issues like medication *approvals* and requirements for medication labeling. Not surprisingly, the words "DEA," "controlled substance," and "Controlled Substances Act" do not appear on Whitelaw's resume. Ex. 1 (Whitelaw Rpt.) at 279-82; Ex. 2 (Whitelaw Tr.) at 88:20-

[1] All Exhibit references are to the declaration of Christopher K. Eppich, submitted herewith.

89:18. Whitelaw's FDA compliance background provides no training or experience with respect to the separate regulatory programs of the DEA.

FDA and DEA are separate regulatory agencies with different statutory and regulatory frameworks. Ex. 2 (Whitelaw Tr.) at 90:5-7, 90:20-91:20. DEA is the federal agency responsible for enforcing the Controlled Substances Act and the requirements governing DEA suspicious order monitoring. Ex. 2 (Whitelaw Tr.) at 90:20-24. FDA is the federal agency responsible for enforcing the Federal Food, Drug and Cosmetic Act and requirements governing the safety of food, drugs, medical devices, cosmetics, and veterinary products. 21 U.S.C. §§ 393. FDA is not charged with enforcing the Controlled Substances Act, and it does not promulgate regulations under the Controlled Substances Act. Ex. 2 (Whitelaw Tr.) at 91:1-20.

B. Whitelaw's Opinions and Methodologies.

Despite his complete lack of qualifications, Whitelaw purports to offer opinions as an expert on suspicious order monitoring programs and the applicable laws and regulations governing the manufacture, distribution, and dispensing of controlled substances. Ex. 1 (Whitelaw Rpt.) at 2. Whitelaw frames the scope of his assignment from plaintiffs as:

- "The relevant standards surrounding the design, implementation, and operation of corporate and controlled substances compliance programs for the pharmaceutical industry."
- "The application of those standards to manufacturers and distributors of controlled substances."
- "The effectiveness of the compliance programs for five distributors and one manufacturer of prescription opioid medicinal products based upon available documentation from 1996 to 2018 ("review period")."

Ex. 1 (Whitelaw Rpt.) at 2.

Although Whitelaw couches the scope of his assignment using the generic term "compliance program," Whitelaw's opinions are directed to highly specialized DEA suspicious

order monitoring programs. Whitelaw first opines on his personal perception of the regulatory framework governing DEA suspicious order monitoring programs, including the Controlled Substances Act and the corresponding DEA regulations. He then identifies the Federal Sentencing Guidelines and standards imposed by the Office of the Inspector General at the Department of Health and Human Services on certain healthcare industries ("OIG Guidance") as the purported foundation for developing controlled substance suspicious order monitoring programs. But neither the Federal Sentencing Guidelines nor the OIG Guidance are used by DEA or industry when developing and evaluating suspicious order monitoring programs.

Notwithstanding, Whitelaw points to eight elements identified in the commentary of the Federal Sentencing Guidelines intended to evaluate whether an organization's program "has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct." Ex. 4 (Federal Sentencing Guidelines, Ch. 8, 1991) at §8A1.2, comment. (n. 3k); Ex. 5 (Federal Sentencing Guidelines, Ch. 8, 2004) at §8B2.1(a)(2); Ex. 1 (Whitelaw Rpt.) at 8-10. These elements are used to evaluate organizations criminally convicted of felonies and Class A misdemeanors, and include "(1) organization and resources; (2) due diligence; (3) written standards; (4) training and communication; (5) monitoring, auditing and investigations; (6) corrective actions; (7) enforcement (i.e., discipline or other consequences for violating the standards); (8) periodic risk assessment." Ex. 1 (Whitelaw Rpt.) at 24. With the understanding that "[t]hese general elements outlined in the Sentencing Guidelines are not pharmaceutical-specific but rather apply to corporations across all industries," Ex. 1 (Whitelaw Rpt.) at 9, Whitelaw points to the OIG Guidance to support his use of the Federal Sentencing Guidelines. He contends "[e]ach [OIG] guidance followed a standard pattern of discussing the elements of an effective compliance program, as articulated by the Sentencing

Guidelines, in the context of that particular industry segment." Ex. 1 (Whitelaw Rpt.) at 11. Whitelaw then proposes "attributes" that he claims will satisfy each of the eight elements in what he characterizes as an "effective" model suspicious order monitoring program. Ex. 1 (Whitelaw Rpt.) at 7-13, 23-44.

Whitelaw then created, with no citation to any publication or accepted practice, his own unverified scoring methodology to compare the attributes of his model program to the suspicious order monitoring programs used by certain defendants. Ex. 1 (Whitelaw Rpt.) at 43-44. Whitelaw conceded that "[m]easuring compliance effectiveness" is not "simply a matter of taking the attributes and applying a statistical, or even a generally recognized standard scoring methodology, ***as one does not exist***." Ex. 1 (Whitelaw Rpt.) at 43 (emphasis added). But he claimed his "compliance maturity and program effectiveness model" created for this litigation is the best approximation of such a methodology. *See id*. At deposition, however, Whitelaw was unable to explain how he applied the model to each defendant or how his model connected to any violation of the Controlled Substances Act. Ex. 2 (Whitelaw Tr.) at 245:12-246:2; 426:5-428:12. Whitelaw then evaluated the suspicious order monitoring programs of defendants McKesson, Cardinal, AmerisourceBergen, CVS, Walgreens, and Mallinckrodt, in comparison to his unverified model. Ex. 1 (Whitelaw Rpt.) at 2-3; Ex. 2 (Whitelaw Tr.) at 245:12-18.

III. ARGUMENT

A. Whitelaw Is Not Qualified to Be an Expert in Suspicious Order Monitoring Programs or the Requirements of the Controlled Substances Act.

As set forth above, Whitelaw offers opinions about suspicious order monitoring programs designed by pharmaceutical manufacturers and distributors pursuant to the requirements of the Controlled Substances Act and its corresponding regulations. Ex. 1 (Whitelaw Rpt.) at 2. But Whitelaw is not qualified to opine on DEA suspicious order monitoring programs. An expert

must be qualified by "knowledge, skill, experience, training, or education" to offer opinions on a particular subject. Fed. R. Civ. P. 702; *Huffman v. Electrolux Home Products*, 129 F. Supp. 3d 529, 537 (N.D. Ohio 2015) ("First, the expert must be qualified to opine on the matter at hand.").

Whitelaw's credentials and experience are unrelated to his opinions in this litigation. Whitelaw's FDA background does not "provide a foundation for [him] to answer a specific question" about suspicious order monitoring programs, the Controlled Substances Act, or DEA regulations. *Huffman*, 129 F. Supp. 3d at 537 (citing *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). This Court has explained that "[e]xpertise in the technology of fruit is not sufficient when analyzing the science of apples, and courts have excluded the testimony of [proffered experts] because their expertise was not particular to the science involved in the case." *Huffman*, 129 F. Supp. 3d at 537 (citing *Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 842 (N.D. Ohio 2011)). It follows that knowledge of FDA regulations does not translate into expertise on DEA matters.

Before this litigation, Whitelaw never held himself out as a "suspicious order monitoring expert." Ex. 2 (Whitelaw Tr.) 829:5-14.[2] Asked to explain how he suddenly became an expert in suspicious order monitoring, Whitelaw cited the work he has done in this litigation. Ex. 2 (Whitelaw Tr.) at 826:16-827:1. He simply lacks the credentials and experience to serve as an

[2] In an attempt to compensate for his lack of credentials, Whitelaw relied on conversations with James Rafalski, a former DEA Diversion Investigator retained by plaintiffs as an expert witness. Ex. 1 (Whitelaw Rpt.) at 4; Ex. 2 (Whitelaw Tr.) 35:4-17; 826:16-827:1. Rafalski, however, testified that he "really didn't see any connection between what [Whitelaw's] opinion was going to be and [his] opinion, but at the request of plaintiff counsels, [they] had a couple of discussions." Ex. 6 (Rafalski Tr.) at 48:17-21. Whitelaw does not rely on any other current or former employee of DEA to support his opinions. Ex. 2 (Whitelaw Tr.) at 36:13-37:6. Even assuming, *arguendo*, that Rafalski was qualified to offer the opinions presented by Whitelaw (and his report does not purport to do so), that would not qualify *Whitelaw* to offer those opinions merely because he spoke to Rafalski.

expert on suspicious order monitoring programs. For example, Whitelaw:

- Never worked at DEA. Ex. 2 at 86:4-7.
- Never worked for a pharmaceutical distributor. Ex. 2 at 86:8-10, 364:22-365:9.
- Never worked for a pharmaceutical manufacturer of controlled substances. Ex. 2 at 70:11-22, 74:16-75:7, 76:21-24, 83:1-6.
- Never designed, operated or audited a DEA compliance program or suspicious order monitoring program for controlled substances. Ex. 2 at 63:16-20, 760:12-761:20.
- Is unable to define basic DEA terminology, such as the meaning of "diversion," without referencing his report. Ex. 2 at 500:10-501:18.

Whitelaw's experience in FDA compliance does not make him an expert in DEA regulations and industry practices regarding suspicious order monitoring at various levels of the supply chain—the issues at the heart of this litigation and the subject matter of his opinions. Whitelaw's FDA background does not qualify him as an expert in other aspects of corporate compliance. As Figure 1 below illustrates, the general subject of corporate compliance has many subtopics, and knowledge of one topic clearly does not translate into expertise about them all.

Figure 1

With no knowledge, skill, experience, training, or education related to suspicious order monitoring programs, the Controlled Substances Act, and DEA regulations, Whitelaw lacks "'specialized knowledge' with regard to the area about which he will testify." *Newell Rubbermaid, Inc. v. Raymond Corp.*, No. 5:08-CV-2632, 2010 WL 2643417, at *3 (N.D. Ohio July 1, 2010) (granting motion to exclude opinions about alleged forklift defect by accomplished mechanical engineer with no specific experience with forklifts), *aff'd* 676 F.3d 521 (6th Cir. 2012); *Huffman*, 129 F. Supp. 3d at 539 ("[A] witness qualifies as an expert when he or she has specialized knowledge, whether by background, experience, or education, in the areas on which the litigation focuses.").

Because Whitelaw's analysis of suspicious order monitoring programs comprises the entirety of his opinions, and he lacks any background or experience in suspicious order monitoring programs, and the Controlled Substances Act and related DEA regulations, the Court should exclude his report and all of his opinions.

B. Grounded in the Wrong Regulatory Framework, Whitelaw's Analysis of Defendants' Suspicious Order Monitoring Programs is Unreliable.

Whitelaw's opinions should be excluded for the independent reason that they are unreliable. "[T]he requirement that an expert's testimony be reliable means that it must be supported by appropriate validation i.e., 'good grounds,' based on what is known. The task for the district court in deciding whether an expert's opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation." *Huffman*, 129 F. Supp. 3d at 537. Whitelaw's lack of expertise led him to use incorrect regulatory standards—including the Federal Sentencing Guidelines and OIG Guidance—to construct his model suspicious order monitoring program. Ex. 1 (Whitelaw Rpt.) at 6, 11-12, 23-44; Ex. 2 (Whitelaw Tr.) at 275:5-276:20; Ex. 7 (Whitelaw Suppl. Rpt.) at 1-5.

1. Whitelaw Improperly Relies on the Federal Sentencing Guidelines and OIG Guidance.

In the context of reliability, Whitelaw's fundamental error is his use of the Federal Sentencing Guidelines as the basis for his model suspicious order monitoring program. Ex. 1 (Whitelaw Rpt.) at 7-11, 23-44. The primary attributes of his model program are "gleaned from," "embedded in," and "come from" Chapter 8 of the Federal Sentencing Guidelines—a set of guidelines used at sentencing for corporate defendants. *See* Ex. 2 (Whitelaw Tr.) at 856:2-23, 880:15-881:1, 904:2-24, 908:12-19. But the Federal Sentencing Guidelines, which have a fundamentally different purpose, say nothing about suspicious order monitoring or diversion control. Ex. 4 at §8A1.1.

Whitelaw testified that "[the Federal Sentencing Guidelines] are where everybody starts. It's where industry starts. It's where compliance professionals start. It's where good companies start et cetera. It is the baseline. It has become the de facto set of standards that you start with when you're looking at and assessing corporate compliance programs." Ex. 2 (Whitelaw Tr.) at 142:13-24; *see also* Ex. 2 (Whitelaw Tr.) at 25:4-5 ("I use the federal sentencing guidelines as my sort of framework."). His testimony on this point, which is wholly ungrounded in either his own experience or the actual practice of anyone who *does* have expertise in this field—is unsupported speculation.

The Federal Sentencing Guidelines do not provide a "reliable foundation." *Huffman*, 129 F. Supp. 3d at 537. Instead, Chapter 8 of those Guidelines on which Whitelaw relies, expressly states that it "applies to the sentencing of all organizations for felony and Class A misdemeanor offenses." Ex. 4 at §8A1.1. Despite expressly applying to criminal sentencings, Whitelaw relies on the guidelines for the purpose of evaluating DEA controlled substance suspicious order monitoring programs. The Federal Sentencing Guidelines are entirely unrelated to the design or

evaluation of suspicious order monitoring programs.

The "industry" does not, as Whitelaw contends, look to the Federal Sentencing Guidelines for suspicious order monitoring programs, and neither does DEA. DEA's Section Chief of the Pharmaceutical Investigations Section of the Office of Diversion Control testified that DEA does not use the Federal Sentencing Guidelines to evaluate Suspicious Order Monitoring Programs:

> Q. The DEA doesn't use the federal sentencing guidelines to evaluate registrants' suspicious order monitoring programs, correct? …
>
> THE WITNESS: Yes. Correct.
>
> Q. Correct that they do not?
>
> A. Do not.
>
> Q. Thank you, sir. Now, when you were training diversion investigators, did you ever instruct diversion investigators to rely on the federal sentencing guidelines to evaluate registrants' suspicious order monitoring programs? …
>
> A. No.

Ex. 8 (Prevoznik Tr.) at 1202:2-20.

Even though Chapter 8 of the Federal Sentencing Guidelines is not about the diversion of prescription medications and is not a reliable foundation for evaluating suspicious order monitoring programs, Whitelaw chose to evaluate the suspicious order monitoring programs of certain defendants using an attenuated interpretation of the Federal Sentencing Guidelines as his "basic framework." Ex. 2 (Whitelaw Tr.) at 142:13-24; Ex. 1 (Whitelaw Rpt.) at 3-4, 7-11. This is not an accepted methodology that can be relied upon to produce reliable results. *Newell Rubbermaid*, 2010 WL 2643417, at *4 ("It is Plaintiff's burden to establish by a preponderance of evidence that her expert's theories are reliable and adequately supported by sound technical data, methodology and testing.") (citations omitted).

Equally problematic is Whitelaw's reliance on standards imposed by the Office of the Inspector General ("OIG") at the Department of Health and Human Services. Ex. 1 (Whitelaw Rpt.) at 11-12. Whitelaw conceded that OIG "never established specific compliance program guidance for pharmaceutical distributors," and that the OIG Guidance does not address or discuss the Controlled Substances Act. Ex. 1 (Whitelaw Rpt.) at 11, n.21; Ex. 2 (Whitelaw Tr.) at 150:12-17. The OIG Guidance on which he relied does not address controlled substances, suspicious order monitoring programs, or distributors at all. *See id.* Thus, Whitelaw's use of the OIG Guidance to evaluate certain defendants' suspicious order monitoring programs is inappropriate and demonstrates an unreliable methodology.

2. Whitelaw's Model Program Created for Purposes of Litigation Should Be Excluded.

Whitelaw's reliance on government guidance documents is particularly surprising because six months before the plaintiffs retained him in this matter, Whitelaw published an article criticizing the OIG and the use of government standards as support for compliance practices:

> Although the government remains steadfast that companies must individually tailor their compliance programs to suit each business and organization, the OIG, among other enforcement bodies, continues to embrace settlement boilerplates and slowly increases the burden and complexity for compliance officers. …
>
> To make matters worse, these much-touted government guidance, settlements, and precedents do not reflect leading practices….
>
> While corporate integrity agreements provide practical frameworks, their purpose is, from an operational compliance perspective, to prevent previous bad conduct and transactions from occurring again. It is a tactical and not a strategic focus. Therefore, the government provides little guidance on how to design and maintain a company culture that encourages ethical decision-making and conduct.

Ex. 9 (Attorney at Law Magazine (March 7, 2018)); Ex. 2 (Whitelaw Tr.) at 277:15-278:11.

After the publication of this article in March 2018, Whitelaw was retained by plaintiffs, paid approximately $480,000.00, and his views transformed:

"To make matters worse, these much-touted government guidance, settlements, and precedents do not reflect leading practices."	"The compliance program guidance also represented the OIG's position on what constituted leading practices at that time for that industry segment."
Attorney at Law Magazine (March 7, 2018)	Whitelaw Expert Report (April 15, 2019)

Whitelaw went forward to write a report that creates, solely for purposes of this litigation, a new model for compliance that is both inconsistent with his own prior views and wholly untethered to any real-world experience. Before this litigation, Whitelaw had never used this model to evaluate a suspicious order monitoring program. Ex. 2 (Whitelaw Tr.) at 715:8-19.

The Sixth Circuit is "suspicious of methodologies created for the purpose of litigation, because 'expert witnesses are not necessarily always unbiased scientists.'" *Mike's Train House, Inc. v. Lionel, LLC*, 472 F.3d 398, 408 (6th Cir. 2006) (quoting *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1352 (6th Cir. 1992)); *see also Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (holding that a "very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying"). That Whitelaw's opinions and analysis were "created for the purpose of litigation" in direct contradiction to his earlier statements militates in favor of their exclusion. *Mike's Train House*, 472 F.3d at 408; *see also Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d at 1317.

Since Whitelaw's analysis is not grounded in a reliable methodology, his model

suspicious ordering monitoring program and his assessments of the suspicious order monitoring programs of McKesson, Cardinal, AmerisourceBergen, CVS, Walgreens, and Mallinckrodt should be excluded under Rule 702.

C. Plaintiffs Offer Whitelaw as an Attorney to Opine on Central Legal Issues.

Whitelaw opines on a central legal issue in this litigation, namely whether certain defendants' suspicious order monitoring systems complied with the Controlled Substance Act and its corresponding DEA regulations. A lawyer serving as an expert witness may not testify as to the ultimate legal issues in the case. *United States v. Geiger*, 303 F. App'x 327, 331 (6th Cir. 2008) ("[W]e have held that an expert witness may opine on a legal conclusion so long as his testimony would not determine an ultimate issue before the jury."). Whitelaw admits that the conclusions he draws would determine the ultimate issue before a jury: whether certain defendants' suspicious order monitoring systems complied with applicable statutes and regulations. Ex. 1 (Whitelaw Rpt.) at 2, 3, 5. For this reason also, his testimony should be excluded as improper expert opinion.

IV. CONCLUSION

For the foregoing reasons, the Court should exclude the opinions of Whitelaw because he is unqualified to testify about DEA suspicious order monitoring programs, his methodology is unreliable, and he purports to offer opinions on an ultimate issue in the litigation.

Dated: June 28, 2019

Respectfully submitted,

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[3] Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion as a result of the Court's deadline to file dispositive and Daubert motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

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CERTIFICATE OF SERVICE

I, Geoffrey E. Hobart, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

/s/ Geoffrey E. Hobart
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